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10/680,705

10/07/2003

Gregory B. Altshuler

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07/24/2006

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EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/680,705 | ALTSHULER ET AL. | |
| | Examiner | Art Unit | |
| | Henry M. Johnson, III | 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of re-evaluation and interpretation of the claims.

The indicated allowability of claims 36-38 is withdrawn in view of re-evaluation and interpretation of the claims. New rejections follow.

Specification

The disclosure is objected to because of the following informalities:

On page 22, lines 25-29, the biostimulation is cited as weaker in region 230, yet the disclosure indicates hyperthermia increases the biostimulation.

On page 25, hypothermia is cited as both suppressing biostimulation (line 11) and increasing biostimulation (line 20).

Page 26, line 24 indicates hyperthermia will be achieved at depths to 30 millimeters, yet for the fluences cited, both figures 6 and 7 show the temperature to drop below 37 °C at a depth of 8 millimeters.

On page 27, line 16, figure 7 is cited as having tabular data. No such data is present. Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show cooling means in Figure 2 as described on page 24 in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing (MPEP § 608.02(d)). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Figure 6 and figure 7 both show depths of skin and subcutaneous fat, yet one has the units in centimeters and the other in millimeters.

Claim Objections

Claims 16, 23 and 40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. No additional method step is provided in the claim. The inherent effect of a previous step is not further limiting.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 23, 40, 43 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23 and 40 are indefinite as the disclosure teaches that cooling may both increase or decrease the efficacy of the biostimulation.

Claim 43 recites the limitation "said volume" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 49 is indefinite as the target area is not part of a device structure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 16, 17, 20-26, 32, 33, 35-45, 47-51, 54, 56, 58 and 62-67 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,273,884 to Altshuler et al.

Altshuler et al. disclose an apparatus and method for irradiating tissue and providing pre-heating and/or pre-cooling to the tissue. Biostimulation within tissue may result from virtually any irradiating of electromagnetic energy. Altshuler et al. teach methods and apparatus for dermatology treatment using radiation, preheating of the treatment volume, precooling, cooling during (simultaneous) treatment and post-treatment (sequential) cooling of the epidermis above the treatment volume and various beam focusing techniques (abstract). Peltier elements (Fig. 2, # 56) are disclosed on either side of a moveable radiation source (Fig. 2, # 50) that provide the heating and cooling from a source separate from the radiation source. The Peltier units

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contact specific areas of tissue that are interpreted as selected first and second portions. The radiation source is disclosed as either coherent or incoherent with the coherent sources including a variety of lasers including diode lasers (Col. 6, lines 24-28). The lasers inherently have narrow bandwidths. Altshuler et al. teaches wavelengths of from 600-1200 nanometers (Col. 11, line 36). Altshuler et al. teaches the heating enhances the radiation effect (Col. 1, lines 16-19). This is interpreted as increasing the efficacy of the biostimulation. Altshuler et al. teaches heating in a range of 40 to 60 °C and cooling in a range from -30 to 20 °C. It is inherent that cooling is used to protect a surface layer of tissue while treating a level below the surface. The device may include a lens or other suitable focusing or non-focusing optical transmission component (Col. 7, lines 59-61). The delivery unit is coupled to the radiation source by a fiber optic cable (Fig. 2, # 32). The device also includes a thermocouple or other suitable temperature sensor mounted close to surface. The temperature sensor connects to controls and may be utilized to control epidermal temperatures or for other suitable purposes (Col. 15, lines 5-8).

Regarding claim 33, Altshuler et al. teaches the use of flowing water, and flowing gas or spray at a desired temperature may be utilized for thermal components (Col. 8, lines 15-17).

Regarding claim 36, with four Peltier elements (Fig. 3) the tissue areas treated would overlap as a temperature gradient would be unavoidable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,273,884 to Altshuler et al. as applied to claim 1 above, and further in view of U.S. Patent Application Publication US 2001/0023363 to Harth et al. Altshuler et al. are discussed above, but do not teach wavelengths below 600 nanometers. A skilled artisan would select the wavelength appropriate for the desired effect. Harth et al. teach a device for treatment of acne with radiation with a wavelength of 405 to 440 nanometers to induce the porphyrins to produce oxygen. The process is biostimulation. Treatment times are disclosed as 15, 30 and 60 minutes. A fan is disclosed that serves to cool and remove excess heat (control temperature) from the treated skin area (paragraph 0058), the fan being an independent source. The intensity on the skin area is disclosed in the range of 10 mW/cm² to 500 mW/cm² (paragraph 0030) and the beam is diverging at a small angle and creates an oval shaped illumination area of typical size 20X10 cm (paragraph 0071) which yields an area of 200 cm². The intensity over a 15 minute interval yields a fluence of 9-450 J/cm².

Claims 18, 19, 27-31, 46 and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,273,884 to Altshuler et al. as applied to claims 1, 39 and 48 above, and further in view of U.S. Patent 5,707,401 to Talmore. Altshuler et al. are discussed above, but do not teach heating using ultrasound or microwave. Talmore teaches a device for

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combining hyperthermic therapy and photodynamic therapy and that combining the two therapies provides benefits (Col. 1, lines 60-67). The treatment consists of radiation with a wavelength of 600-750 nanometers and an intensity of 100-150 mW/cm². An Xe lamp provides radiation in the stated wavelengths and heating is provided by a CO₂ or Nd:YAG laser (Col. 3, lines 40-49). Nd:YAG lasers typically emit light with a wavelength of 1064 nm, in the infrared. Heating of tissue using alternative equivalents of a laser are well known to one skilled in the art. Flashlamps, electrical resistance heaters, ultrasound and microwave are such heating means and therefore it would have been obvious to one skilled in the art to use alternative heating means as taught by Talmore in the invention of Altshuler et al. as such means are neither new or novel.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,273,884 to Altshuler et al. as applied to claim 1 above, and further in view of U.S. Patent 6387089 to Kreindel et al. Altshuler et al. are discussed above, but do not teach a cream for adjusting temperature. Kreindel et al. disclose an apparatus and method for wrinkle smoothing using radiation with a range of 600-1600 nanometers (Col. 2, line 36) and cooling the treated area with ice, a gel or a crystal in contact with the surface (abstract). Ice teaches vaporization and gel is interpreted as a cream. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use cooling methods as taught by Kreindel et al. in the invention of Altshuler et al. as such evaporation cooling is common and well known in the art.

Claims 55, 57, 59-61 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,273,884 to Altshuler et al. Altshuler et al. are discussed above and teach various lenses for directing and focusing the radiation on a target area including a beam splitter (Fig. 12B) and a prism (Fig. 11B). The optics for directing and forming radiation for delivery are

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well known to one of ordinary skill in the art and it would be obvious for a skilled artisan to configure an optical system consistent with the radiation and target area.

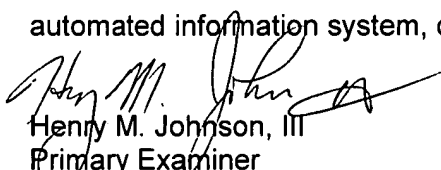
Regarding claim 68, a skilled artisan would move a delivery handpiece as appropriate to provide the desired fluence to the target area.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Henry M. Johnson, III
Primary Examiner
Art Unit 3739